4/28/99

K984223

510(k) SUMMARY

Citizen Watch Company, Ltd.
Models CH-491, CH-481, and CH-471
Blood Pressure Meters

SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON AND DATE PREPARED

Citizen Watch Company, Ltd.
Medical Device Section, NP Development Department
1-12, 6-Chome, Hon-cho
Tanashi-shi, Tokyo, 188 JAPAN

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Date Prepared: November 24, 1998

NAME OF DEVICE

Trade Name: CH-491, CH-481, and CH-471 Blood Pressure Meter
Common Name: Digital Arm Sphygmomanometer (blood pressure meters)
Classification Name: System, Measurement, Blood Pressure, Non-Invasive (21 C.F.R. § 870.1130)

PREDICATE DEVICE

(1) Citizen Watch Company, Ltd. CH-401 Blood Pressure Monitor

INTENDED USE

The Citizen CH-491, CH-481 and CH-471 digital arm sphygmomanometers (blood pressure meters) are intended to be used for oscillometric measurement of systolic and diastolic blood pressure and pulse and intended to be sold over-the-counter and to health care professionals, and not primarily under the order or direction of a physician.

DEVICE DESCRIPTION

The Citizen CH-491, CH-481 and CH-471 digital arm sphygmomanometers are noninvasive blood pressure measurement systems that measure systolic and diastolic blood

pressure and pulse from the user's upper arm. The units are contained in a hard plastic housing that contains a user interface panel, microprocessor and air pump and is connected byu tubing to an adjustable arm cuff. The user interface panel has a power switch, a start switch, and a liquid crystal display ("LCD"). The user interface panel for the CH-481 has an additional switch to control the memory function, while the user interface panel for the CH-491 has additional switches to control the clock and memory functions.

The device measures blood pressure through the use of an automatically-inflating arm cuff. The cuff automatically deflates during blood pressure measurement. Model CH-471 has a memory function that displays the last blood pressure readout when the system is turned on. Model CH-481 has a memory function that allows the user to retain seven (7) prior blood pressure measurements. Model CH-491 has a memory function that allows the user to retain thirty (30) prior blood pressure measurements and also includes an LCD display that shows blood pressure measurement in a graph format.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Citizen models CH-491, CH-481, and CH-471 represent design changes over the Citizen model CH-401 with respect to the method and procedure for inflation and deflation of the arm cuff. Model CH-491 also adds a clock/watch function and all models have a modified LCD display.

Citizen has determined that these changes have no influence on the correct measuring and the accuracy of systolic and diastolic blood pressure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 1999

Citizen Watch Co., Ltd
c/o Mr. Joseph D. Edmondson, Jr., Esq.
Counsel for Citizen Watch Co., Ltd
Foley & Lardner
3000 K Street, NW, Suite 500
Washington, DC 20007-5109

Re: K984223
Blood Pressure Meter, Models CH-491, CH-481 and CH-471
Regulatory Class: II (Two)
Product Code: 74 DXN
Dated: March 29, 1999
Received: March 30, 1999

Dear Mr. Edmondson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K98-4223

Device Name: Blood Pressure Meter, Models CH-491, CH-481 and CH-471
Citizen Watch Co.

Indications For Use:

The Citizen CH-491, CH 481 and CH-471 digital arm sphygmomanometers (blood pressure meters) are intended to be used for oscillometric measurement of systolic and diastolic blood pressure and pulse in adults and are intended to be sold over-the-counter and to health care professionals, and not primarily under the order or direction of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984223

Prescription Use ___ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)